DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 8, 2014

Boston Scientific Corporation
Liz Johnston
Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311-1566

Re: K141378
Trade/Device Name: IDC Interlocking Detachable Coils
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: August 15, 2014
Received: August 18, 2014

Dear Liz Johnston:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141378

Device Name
IDC™ Interlocking Detachable Coil

Indications for Use *(Describe)*
The IDC Coil is a modified interlocking detachable coil indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Per 21 CFR §807.92

Submitter's Name and Address:

Boston Scientific Corporation
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USA

Contact Information:

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Regulatory Affairs Specialist II
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Date Prepared: 23May2014

Proprietary Name: IDC™ Interlocking Detachable Coil

Common Name: Vascular embolization device

Classification:

Class II
Product Code: KRD
Review Panel: Cardiovascular

Predicate Device:

Interlocking Detachable Coil System (IDC)
K040342 - April 13, 2004

Intended Use / Indications for Use:

The IDC Coil is a modified interlocking detachable coil indicated to obstruct or reduce rate of blood flow in the peripheral vasculature. This device is not intended for neurovascular use.

Device Description:

The IDC Coil includes a standard or soft coil (manufactured from platinum-tungsten alloy) that is mechanically attached to a coil delivery wire. This assembly is contained within an introducer sheath. The IDC Coil is designed to be delivered under fluoroscopy with a 0.53 mm (0.021 in) inner diameter (I.D.) microcatheter (e.g. Renegade™ Microcatheter) with one radiopaque (RO) tip marker. The interlocking delivery wire design allows the coil to be advanced and retracted before final placement in the vessel, thus aiding in more controlled delivery including the ability to withdraw the coil prior to deployment.

Comparison of Technological Characteristics:

The IDC Interlocking Detachable Coil are similar in fundamental design, function, device materials, packaging, sterilization, operating principle, intended use / indication for use and fundamental technology as the predicate device.

Performance Data:

The MRI testing results conducted under methods described by ASTM F2182-02a, ASTM F2052-06e1, ASTM F2213-06 and ASTM F2119-07 have demonstrated that the peripheral coils are to be MR Conditional and can be scanned safely under a static magnetic field of 1.5 Tesla or 3.0 Tesla.

Testing at field strengths other than 1.5 Tesla or 3.0 Tesla has not been performed to evaluate coil migration or heating.

Conclusion:

The modifications do not affect the intended use or alter the fundamental scientific technology of the predicate Boston Scientific Interlocking Detachable Coil System (K040342).

Based on the Indications for Use, unaltered technological characteristics, and submitted non-clinical performance data supporting this modification, the Boston Scientific IDC Interlocking Detachable Coil is shown to be appropriate for its intended use and demonstrates that the device is as safe, as effective, and performs as well as the predicate device.